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Award Number: W81XWH-11-2-0129

TITLE: PHIT for Duty, a Personal Health Intervention Tool for Psychological Health and Traumatic Brain Injury

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REPORT DATE: April 2012

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE *(DD-MM-YYYY)*	**2. REPORT TYPE**	**3. DATES COVERED** *(From - To)*
01-04-2012	Annual	15 Mar 2011 - 14 Mar 2012

4. TITLE AND SUBTITLE
PHIT for Duty, a Personal Health Intervention Tool for Psychological Health and Traumatic Brain Injury

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-11-2-0129

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Research Triangle Institute
Research Triangle Park, NC 27709

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

The purpose of this project is to help prevent psychological disorders in high-risk individuals with early symptoms of stress, depression, substance use, and other health problems. Military medicine is increasingly concerned with the incidence of psychological casualties and the treatment of post-traumatic stress disorder (PTSD) in returning personnel. This incidence increases the need for medical care and reduces operational readiness. Few preventive methods are available to mitigate subclinical psychological health issues upon the return of personnel from deployment. The PHIT for Duty system is a personal health intervention tool (PHIT) using mobile smartphone technology to integrate personal health assessment with targeted self-help intervention for the mitigation of psychological symptoms, modification of risky behaviors, and provision of cognitive support. The study will identify self-help interventions to assist individuals in dealing with combat and operational stress; develop smartphone applications for health assessment and self-help intervention; and evaluate the PHIT methodology for prevention of psychological disorders in post-deployed personnel. Improvements in patient-related outcomes are expected to be demonstrated in 2-3 years. The PHIT for Duty mobile health approach can be transitioned for chronic disease management, obesity prevention, substance use intervention, and other domains where better personal health management could improve wellness and clinical outcomes.

15. SUBJECT TERMS
PTSD, post-traumatic stress disorder, mobile health, smartphone, self help

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON**
a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**			USAMRMC
U	U	U	UU	17	**19b. TELEPHONE NUMBER** *(include area code)*

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1. INTRODUCTION

The goal of this project is to support prevention of psychological health problems and post-traumatic stress disorder (PTSD) through innovation in mobile personal health assessment and self-help intervention (SHI).

Our objective is to develop and evaluate PHIT for Duty, a field-deployable personal device to help build resilience in healthy troops and support prevention in high-risk personnel. Based on RTI's Personal Health Intervention Tool (PHIT) platform, PHIT for Duty will integrate a suite of health assessments with an intelligent virtual advisor (iVA) that recommends, tailors, and presents self-help advisories based on established rules and processes. The PHIT platform will comprise a smartphone or tablet and optional, nonintrusive physiological and behavioral sensors for health status monitoring and intervention.

PHIT for Duty is intended to be used for secondary prevention of psychological health problems in persons who have been exposed to psychological trauma and may be having some symptoms of distress, but have not been diagnosed with any psychological disease or disorder. PHIT for Duty, however, may eventually prove useful as a treatment option, and therefore should be developed according to good software development practices.

The project comprises (1) formative research to identify psychological assessments and SHIs to assist individuals in dealing with combat and operational stress and the psychological and physiological consequences of that exposure; (2) development of personal, mobile technologies for longitudinal health assessment and SHI; (3) testing, refinement, and validation of PHIT for Duty technologies through beta testing and pilot studies; (4) evaluation the efficacy of the PHIT methodology for prevention in a randomized controlled trial (RCT) with post-deployed personnel; and (5) adapting the developed system for several popular smartphone or tablet computer platforms, including both Google Android™ and Apple iOS based devices.

2. BODY

2.1. Task 1: Concept formation and development planning

The goal of this task is to establish the vision, requirements, and approach for PHIT for Duty development and evaluation through a series of interactions with scientific and clinical advisors, military leaders, prospective users, and other stakeholders. Our objective is to identify preventable psychological health problems that might be mitigated using PHIT for Duty, potential self-help interventions to incorporate in the device, operational issues regarding PHIT for Duty use post deployment, and the applicability and potential concerns for PHIT for Duty during deployment. In additional, we will identify

scientific and technical requirements for PHIT design and implementation. The result will be qualitative and quantitative documentation supporting PHIT for Duty design, development, and evaluation.

2.1.1. Focus groups

To identify user and stakeholder requirements, interests, and concerns for PHIT usage in real-life applications, we will be conducting a series of focus groups comprising post-deployed service members, medical corpsmen, chaplains, unit leaders, and civilian and military mental health professionals. Early in the project, we met with officials at Womack Army Medical Center (WAMC), Fort Bragg, NC, and established arrangements to conduct the focus groups at Fort Bragg. COL Jay E. Earles, Chief, Department of Behavioral Health, agreed to collaborate on the focus groups, and the overall project.

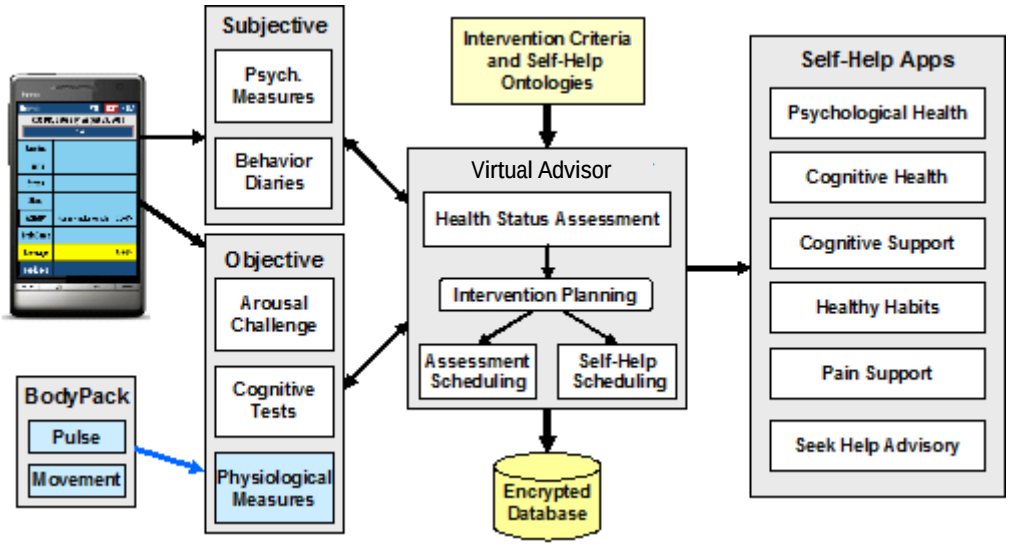
RTI investigators prepared a protocol, including consent form, recruitment processes, and a focus group interview guide, and submitted the protocol to the RTI Institutional Review Board (IRB) for review. After the RTI approval was granted on 19 August 2011, COL Earles submitted the protocol to the WAMC IRB, from which approval was granted on 10 February 2012. The Human Research Protection Office (HRPO) then gave its approval on 29 February 2012. On 05 April 2012 the RTI team met with COL Earles to begin the focus group process, identifying key informants who will be contacted in the next few weeks to refine focus group questions. Conduct of the focus groups is planned for April and May 2012.

2.1.2. Concept formation

The PHIT vision is to integrate personal health assessments, observations in daily living, and health intervention strategies in a mobile, personal platform (**Exhibit 1**). Baseline information and subjective data are entered using self-report forms and questionnaires. Objective data are acquired via interactive smartphone exercises and physiological sensors. To assess cardiac stress reactivity, physiological arousal, and sleep quality, small devices provide sensors for heart rate (HR), heart rate variability (HRV), and body motion and transmit data to the smartphone via Bluetooth wireless. The planned suite of assessments is comprehensive; however, we do not intend that all will be measured on each individual or at the same time. Rather they will be scheduled over time to minimize burden.

The PHIT approach mimics the SOAP notes (e.g., subjective, objective, assessment, plan) workflow model commonly used in primary care settings (Larimore & Jordan, 1995). This process model, coupled with self-help resources for prevention and treatment, provides a new facilitated paradigm for personal health assessment and management. Subjective psychometric measures (e.g., sleep quality, mood) and self-reported behaviors (e.g., alcohol use, exercise) are combined with objective measures (e.g., HRV arousal measures) to form an overall health status assessment. An intelligent virtual advisor (iVA) uses the assessment to plan self-administered interventions, such as sleep hygiene education, stress relaxation exercises, and substance use reduction skills acquisition.

Exhibit 1. System Architecture for the Personal Health Intervention Tool



At set intervals (e.g., weekly, biweekly) the PHIT iVA will notify the user that one or more health instrument data inputs are requested from the set of primary health domains (PTSD, depression, anxiety, stress, alcohol use). Scheduled instrument and intervention tasks will be listed on the smartphone's top screen. After the user completes each instrument, the iVA will conduct a health status assessment according to predefined evidence-based rules and diagnostic criteria for each domain. If certain thresholds are exceeded, the iVA will recommend SHIs by listing them on the top screen. Other updates to the task list, such as scheduling additional or alternate instrument inputs, may also be made by the iVA. Self-help advisories will be made using logic scripts with criteria thresholds linking assessment measures to available SHI applications.

As an example, while completing a sleep assessment log the user might note periods of anxiety and insomnia. The iVA would score these assessments and recommend several SHIs, such as stress relaxation training and sleep hygiene therapy, to improve sleep quality. If the user continued to report sleep problems, the PHIT would request that actigraphy and HR sensors be used during several subsequent nights to acquire objective measures of sleep quality. Further reported sleep problems would then lead the iVA to refer the user to a clinician. All of these data would be logged and uploaded to a secure database for quality assurance review by study personnel, and subsequent data analysis.

2.2. Task 2: Prototype design and development

2.2.1. Overall system architecture

One of our goals is to create a common mobile health platform from which many other mobile health management and data gathering applications can be readily developed, and to experiment with alternative ways of configuring the data input instruments. The PHIT system accomplishes this, in part, by integrating different forms of data inputs ranging from survey style questionnaires to diaries to external physiological and environmental sensors.

To create a common mobile health platform from which many other mobile data gathering applications can be developed, we created a framework with four primary components (**Exhibit 2**):

- Task manager – Handles the dynamic user task list of instruments and activities (**Exhibit 3**). It also handles scheduling user events, e.g., a particular data collection instrument should appear on the task list only on Friday mornings at 8am.
- Instrument manager – Handles collecting input data. PHIT supports many different instruments such as:
    - Surveys and questionnaires
    - External sensors
    - Multimedia presentations (e.g., information about stress management)
- Intelligent virtual advisor – Executes assessment logic on input data and modifies the task list as appropriate.

Exhibit 2. Primary Components of the Personal Health Intervention Tool

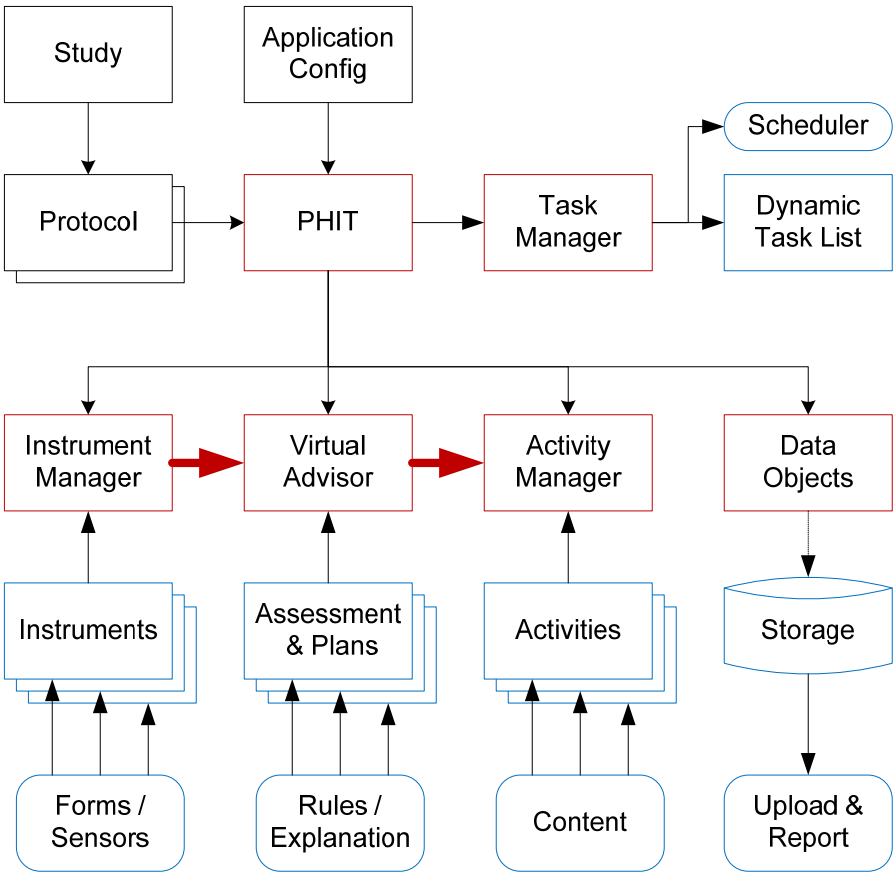
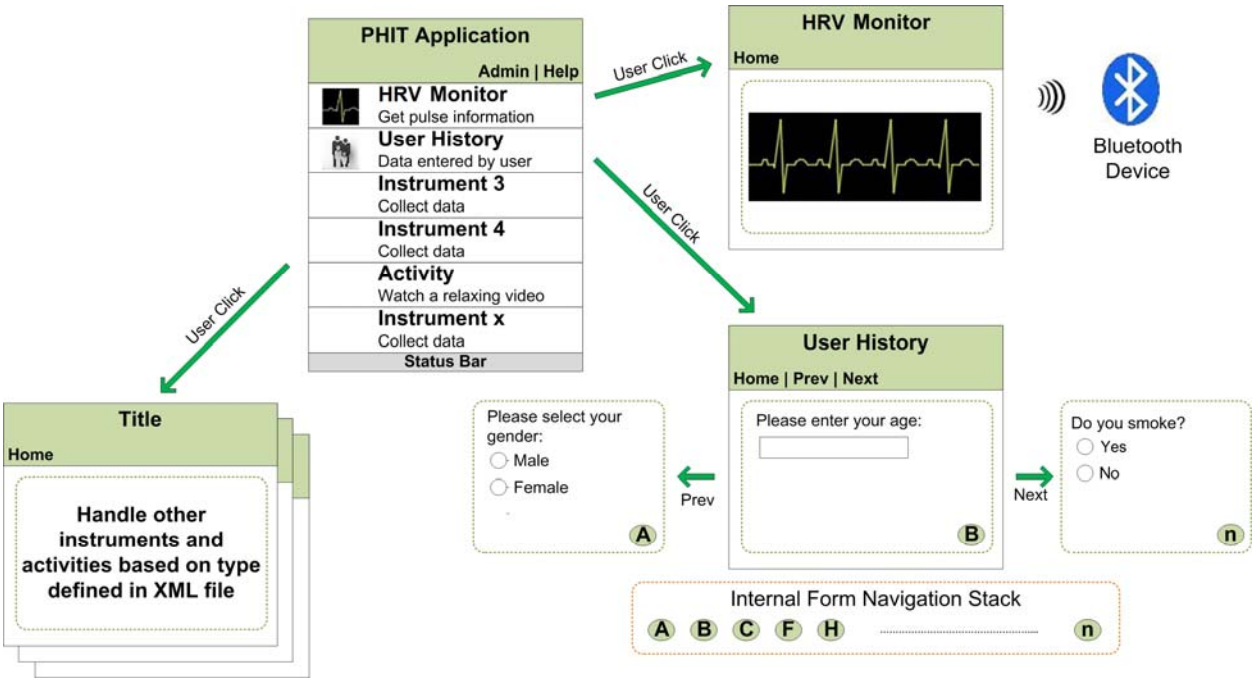


Exhibit 3. PHIT User Interactions



- Activity manager – Handles output activities that result from the processing of the input data such as:
    - Self-help interventions
    - Charts and reporting
    - User notifications (e.g., advisory to seek professional medical evaluation and care)

After the system collects data via the various instruments, the iVA processes the data by applying rules to the collected data. It decides if further data need to be collected or if the user should perform a series of activities. For instance, anxiety or stress data might be collected using external sensors. The iVA, after analyzing the data, could display relaxation activities on the task list.

All systems are XML configurable making it easy for us to experiment with alternative ways of configuring the data input instruments. Instrument XML contains logic that can perform dynamic lookups, validate data and modify data collection sequencing.

The system provides a secure login and data are stored in an encrypted database with optional periodic synchronization to a backend server. Personally identifiable information and other collected data, when uploaded, will be multiply encrypted to protect against upload security risks. The system XML configuration can be downloaded on-demand. The built-in logic processor executes custom logic to change the behavior of the application and display custom output using different forms of media.

To ensure the reusability of the PHIT framework, we have developed many reusable instrument types which describe what kind of data each particular instrument collects. The logic how to interpret that data is configured in the specific application XML for a particular instrument.

Each instrument contains forms which comprise one or more I/O entities. An entity generally is a collected data element, e.g., age, blood pressure, or pulse rate. The entity type describes what GUI element to display to collect that data. Thus, age might be collected via a text input field, blood pressure might be collected via an attached monitor, and pulse rate might be collected from a Bluetooth connected device. Entities may also provide information via html-formatted text, images, and video, and slideshows with audio narrative. The PHIT framework supports many different entity types for reuse across all PHIT applications. Some instruments have no GUI but merely execute functions or initiate data collection via external sensors and devices. Data collected are automatically saved for evaluation by the iVA.

The task list displays all the tasks the user may interact with at that point in time. The background scheduler ensures that only pertinent tasks are displayed, depending on a previous user response, a determination by the iVA to collect specific information, or the reaching of a certain point in time (e.g., Friday 8am). Each instrument knows how to collect its own data and the logic in the XML allows for custom application flows.

2.2.2. Psychometric assessment and scheduling

Based on the design inputs set by our internal science team, a suite of psychological, behavioral, social, and other health assessments has been developed and is now in testing. Each assessment instrument (e.g., Beck Anxiety Inventory) was scripted using an XML-based language as specified in the PHIT architectural documentation. The science team has also scripted the iVA logic, which will direct the scheduling of instruments based on a set of logic rules.

These health assessments comprise a range of health domains (**Exhibit 4**), including trauma exposure, PTSD symptoms, anxiety, depression, sleep quality, and substance use. Some measures will be taken only at baseline, such as the Combat Exposure Scale. Others will be taken periodically (e.g., weekly) as screeners, and if instrument-specific thresholds are exceeded, a more detailed assessment will be made via another instrument. The status of these periodic health assessments will be used to recommend stratified self-help interventional activities to be carried out by the user on the smartphone. The decisions about which screeners, instruments, and SHI to present will be made by the iVA. Design and development of software for these interventional activities, such as cognitive therapy for anxiety, will be done during the second year of the project.

Exhibit 4. Self-assessment Instruments Implemented for the PHIT for Duty Study

Baseline instruments

Personal Data	User Demographics and History	n/a
Combat exposure	Combat Exposure Scale (CES)	Keane et al., 1989
Head injury	Concussion Checklist (CCL)	McCrory et al., 2004
Coping	Brief Coping Scale (BCOPE)	Carver, 1997
Resilience	Connor-Davidson Resilience Scale (CDRS)	Connor et al., 2003
Emotional Regulation	Difficulties in Emotion Regulation Scale DERS)	Gratz and Roemer, 2004
Distress	Impact of Event Scale (IES)	Horowitz et al., 1979

Monitoring instruments

Primary measures

PTSD	Short Screening for PTSD (PTSD7)	Breslau et al., 1999
Sleep	Pittsburgh Sleep Quality Index (PSQI)	Buysse et al., 1989
Alcohol	The CAGE Questionnaire (CAGE)	Ewing, 1984
Anxiety	General Anxiety Disorder (GAD7)	Spitzer et al., 2006
Depression	Beck Depression Inventory for Primary Care (BDIPC)	Beck et al., 1996

Secondary measures

Stress	Perceived Stress Scale-4 (PSS4)	Cohen et al., 1983
Social	Multidimensional Scale of Perceived Social Support	Zimet et al., 1988
TBI	The Brief Traumatic Brain Injury Screen (TBI3)	Schwab et al., 2006

Full-scale assessment instruments

Primary measures

PTSD	PTSD Checklist-Military (PCLM)	Weathers et al., 1993
Sleep	Pittsburgh Sleep Quality Index (PSQI)	Buysse et al., 1989
Alcohol	Alcohol Use Disorder Identification Test (AUDIT)	Babor et al., 2001
Anxiety	Beck Anxiety Inventory (BAI)	Beck et al., 1988
Depression	Beck Depression Inventory (BDI)	Beck et al., 1961

Secondary measures

Stress	Stress Questionnaire (STRESSOR)	
Social	Multidimensional Scale of Perceived Social Support	Zimet et al., 1988
TBI	Rivermead Post Concussion Symptoms Questionnaire (RPQ)	King et al., 1995

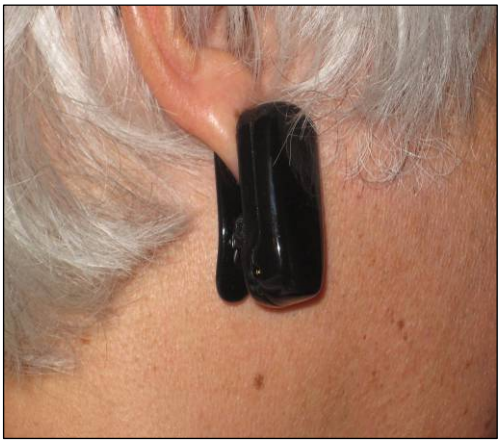
Supporting instruments

Sleep	Pittsburg Sleep Quality Index Addendum (PSQIA)	Germain et al., 2005
Stress	Perceived Stress Scale-10 (PSS10)	Cohen et al., 1983
Reactivity	Simple Reaction Time	

2.2.3. Psychological arousal

For objective measurement of psychological arousal, we are developing a system comprising a wireless pulse sensor clipped to the earlobe (**Exhibit 5**) and software to display ear pulse, heart rate (HR), and heart rate variability The pulse sensor (Binar HeartSensor model HRS-08WE, Binar Integrated Mobile Systems, LLC, Poulsbo, WA) is a very small and unobtrusive device linked to the smartphone via a Bluetooth wireless connection, and therefore can be used to assess cardiac arousal almost anywhere and anytime. We have tested the device during a range of activities at rest and during exercise, and have found the ear pulse wave to be free of artifacts and usable up to 4 hours on a battery charge.

Exhibit 5. Wireless Pulse Sensor



To support psychological arousal assessment, we are developing a cardiac pulse data collection module for the PHIT framework based on previous work (Kizakevich, 2010). Data acquisition will begin with a monitoring screen displaying cardiac pulse waveform, an HR trend chart, and an HRV trend chart. After verification of the apparent quality of the cardiac pulse and HR information, a time-stamped recording of beat-to-beat cardiac intervals (i.e., RR intervals) will be acquired to a data file. HRV and a psychological arousal index will be displayed for user biofeedback during stress relaxation training.

2.2.4. Sleep quality

Since sleep problems are frequently associated with hyperarousal and PTSD (Gellis et al., 2010), we proposed to develop some measurement technology for objective assessment of sleep quality, rather than a mere questionnaire (e.g., PSQI), that could be used in near real time with smartphones or other portable devices. Actigraphy, which employs motion sensors attached to the wrist, is an obvious candidate; however the commercially-available systems do not interface with smartphones. Furthermore, actigraphy has been found to be better in assessing sleep/wake cycles rather than sleep quality (Pollak et al., 2001). Consequently we were looking at alternatives.

Since persons having sleep disturbance often describe their bedtime experience as “tossing and turning”, in earlier work we developed a new sleep assessment methodology comprising a wireless accelerometry sensor clipped to a torso band and software to capture 3-axis motion data continuously throughout bedtime to a smartphone (Kizakevich, 2010). Sleep data are then processed for a variety of measurements that may be useful in determining sleep quality. Regrettably, the body motion sensor we intended to use is no longer on the market. We proceeded to design our own electronic sensor, but have

deferred further development pending identification and review of and commercially available technology that address our needs.

One newly-available device that we have begun to evaluate is the Zeo Sleep Manager (Zeo Inc., Newton, MA). This validated device (Shambroom et al., 2012) uses an unobtrusive headband (**Exhibit 6**) to sense sleep patterns and send the data wirelessly to a mobile device, on which the patterns of REM, light, and deep sleep and wakefulness are charted. We will continue to evaluate the use of the Zeo during our focus groups and beta testing and determine whether to use this device in the main study.

Exhibit 6. Zeo Headband

2.3. Task 3: Beta testing in civilians

This task will involve evaluating the usability, technical functionality, and operational effectiveness of the PHIT device in a civilian population that is representative of the full study's military population. We will identify and remediate any problems in user interactions, functional processes, and technical performance. This aim ensures that the PHIT prototype performs as designed and that the usability of the developed systems is effective for a typical individual using PHIT for up to four weeks. The protocol for beta testing was approved by RTI's IRB on 9 January 2012 and has been submitted to HRPO for continuing Army approval.

2.4. Task 4: Pilot study in service members

Initial planning discussions have been held with COL Earles at WAMC. The issue at this early stage is whether Fort Bragg is the most appropriate place to conduct the pilot study and randomized controlled trial. COL Earles is quite confident that with the size of the Fort Bragg population and the availability multiple points of access to prospective participants through primary care facilities and psychological screenings, that we should have no difficulty in recruiting the necessary number of participants to our studies.

2.5. Task 5: Randomized controlled trial in post-deployed personnel

No work to date.

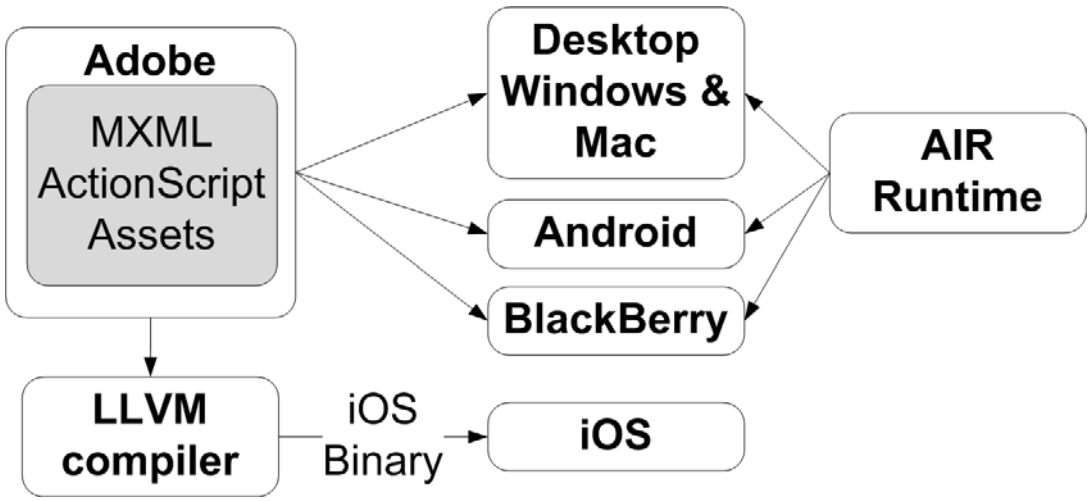
2.6. Task 6: Migration to other smartphones and tablets

As mobile devices become more prevalent, so does the range of possibilities for medical applications to gather data using these devices. Since the user community employs a variety of technologies, and development tools vary across platforms, engineers generally select a single platform for development. This approach reduces the number of devices the application can run on, reduces new features, and imposes additional cost while the team re-implements the application for different smartphone and tablet devices.

To avoid these issues, we examined several cross-platform development tools to determine their efficacy and applicability for PHIT development. The result was our selection of Adobe Flash Builder for software development and the Adobe Interactive Runtime (AIR) for execution on multiple mobile platforms (**Exhibit 7**). Applications developed for Adobe AIR will not only execute on devices using the Google Android and the Apple iOS operating systems, but also on Microsoft Windows and Apple desktop computers. (Due to limitations of the platform, we will not support BlackBerry versions.) Of course not all of the application features may be supported on all devices, such as GPS location identification, as such resources are not universally available. However, the PHIT software is designed to tailor itself to those resources that are available, and for which the user has govern permission.

Using Adobe Flash Builder, software is developed in Adobe Actionscript, an advanced object-oriented language that is very similar to Java and Javascript. User screens are designed using MXML, an object-oriented layout language for media-rich interactive graphical interfaces. Packaging for Android or iOS is as easy as selecting the particular export platform when building the project. For Android, the package requires the Adobe AIR runtime to be installed on the mobile device. For iOS, a native iOS binary is generated which includes all necessary runtime support.

Exhibit 7 Cross-platform development methodology using the Adobe AIR runtime



3. KEY RESEARCH ACCOMPLISHMENTS

To date the main research accomplishments have been technical and formative. The generic platform upon which PHIT is being built is highly extensible, flexible, and secure. Developing PHIT components such as instruments, activities, and iVA modules is straightforward yet the XML structures provide considerable power in customizing the content. For example, subscores and the overall score for a user for a questionnaire (e.g., for anxiety) is immediately available to the iVA, which is able to determine how to proceed with the user. The iVA may choose to schedule a screening for a future date, to place a SHI on the user's task list, or, if necessary, contact a clinician for referral. Variations of instruments, new

instruments that focus group participants suggest are important, and advisory content that improves the PHIT device's usability are all able to be easily accommodated.

Additionally, we have worked with clinical experts to implement a range of domains and instruments that are evidence-based, and thus justifiable. For example, the primary domains () are those that clinicians feel are most important to the target population for PHIT, and the iVA's underlying algorithms are written to carefully consider variation in assessments of these domains. Other data (e.g., resilience, combat exposure, and family history) are captured through additional validated and custom instruments that will be used as covariates in analyses to better explain trends found in the main domains.

4. REPORTABLE OUTCOMES

4.1. Manuscripts, abstracts, presentations

The following presentations were made reporting on work from the project:

Kizakevich, P.N. (2012, January). Mobile technologies for health monitoring and intervention. Invited presentation, Raleigh Engineers Club, Raleigh, NC.

Eckhoff, R.P., Kizakevich, P.N., Zhang, Y., & Hubal, R.C. (2012, February). Personal Health Intervention Tool: A mobile framework using Adobe Flash Builder. Poster presented at the Digital Health Communication Extravaganza, Orlando, FL.

Hubal, R. (2012, April). The imperative for social competency prediction. Talk presented at the Social Computing, Behavioral Modeling and Prediction Conference, College Park, MD.

4.2. Licenses applied for and/or issued

- No patents or disclosures have been filed.
- RTI plans to copyright the PHIT platform and PHIT for Duty source code and application.
- The PHIT platform may be recognized as a medical device; currently an investigational device exemption has been granted by RTI's IRB.

4.3. Degrees obtained that are supported by this award

None

4.4. Development of cell lines, tissue or serum repositories

Not applicable

4.5. Infomatics such as databases and animal models

None

4.6. Funding applied for based on work supported by this award

The Office of Naval Research has awarded a contract to RTI International for related work (ONR N00014-11-C-0129). This project, also called PHIT for Duty, a Personal Health Intervention Tool for Psychological Health and Traumatic Brain Injury, will support the overall PHIT research and development program with studies designed to validate aspects of the PHIT methodology, software applications, and hardware platform. Specifically, we will conduct the following two studies to validate methods for assessing psychological health that will be incorporated in the PHIT for Duty system.

Mini-study 1: Evaluate the efficacy of PHIT psychological arousal and sleep quality assessment methodologies. For psychological arousal, the objective is to evaluate heart rate variability monitoring for measurement of arousal and the efficacy of PHIT SHIs for stress relaxation training. These assessments will be conducted by comparing PHIT-derived measures with standard noninvasive methods of assessment, such as changes in skin conductivity. For sleep quality assessment, the objective is to evaluate body motion monitoring via noninvasive accelerometry for body posture and movement assessment during sleep. These assessments will be conducted by comparing PHIT-derived measures with standard noninvasive methods of assessment, such as wrist-motion actigraphy.

Mini-study 2: Evaluate the accuracy of psychological assessment scores. The objective is to evaluate how well the self-conducted psychological health assessments incorporated in the PHIT for Duty platform compare with standardized assessments being conducted by trained clinical professionals.

4.7. Employment or research opportunities applied for and/or received based on experience/training supported by this award

None

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